UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

STEUBEN FOODS, INC.,		**DECISION AND ORDER**
v.		
	Plaintiff,	**1:10-cv-00780-EAW-JJM** **1:10-cv-00781-EAW-JJM**
OYSTAR GROUP *et al.*,		**1:12-cv-00904-EAW-JJM** **1:13-cv-00892-EAW-JJM**
	Defendants.	**1:13-cv-01118-EAW-JJM**

Familiarity with the relevant background of these patent infringement actions is presumed. Although we had agreed on yet another round of briefing at the conclusion of the April 10, 2018 proceeding [500],[1] upon further reflection I believe that I have enough information to properly construe the phrase "aseptically disinfecting" as used in the patents in suit. For the reasons discussed in Point A of this Decision and Order, I conclude that the phrase does not necessarily preclude the use of oxonia as the sterilant.[2]

However, construction and validity are "separate issues that must be separately addressed". Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911–12 (Fed. Cir. 2004). Therefore, "a decision with respect to claim construction does not constitute an implicit ruling that the construed claims are valid". Xerox Corp. v. 3Com Corp., 61 Fed. App'x 680, 683 (Fed. Cir. 2003); Degelman Industries Ltd. v. Pro-Tech Welding & Fabrication, Inc., 630 F. Supp. 2d 273, 280 (W.D.N.Y. 2008). For the reasons discussed in Points B and C, it appears to me that the

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[1] Unless otherwise indicated, bracketed references are to CM/ECF docket entries in 12-cv-904, and page references are to the documents themselves rather than to CM/ECF pagination.

[2] Judge Wolford has stated that "[c]laim construction issues are often dispositive of the parties' claims and defenses in a particular case". Fisher-Price, Inc. v. Kids II, Inc., 2015 WL 2401887, *1 (W.D.N.Y. 2015). My construction of "aseptically disinfecting" will be incorporated into a Report and Recommendation to issue at the conclusion of the proceedings described herein.

question of whether Steuben's patents can validly be applied (as oppose to construed) to cover the use of oxonia as the sterilant is amenable to summary judgment.

DISCUSSION

A. Can "Aseptically Disinfecting" be Construed to Preclude the Use of Oxonia?

In a word, no. The patent specifications state that "the present invention uses an aseptic sterilant such as hydrogen peroxide . . . or oxonia to sterilize the bottles" ('013 patent [1-1], col. 4, l. 50-51; '188 patent [426-3], col. 4, l. 48-50), and define oxonia as "hydrogen peroxide and peroxyacetic acid". '013 patent, col. 13, l. 26-27; '188 patent, col. 13, l. 26-27.

Notwithstanding those statements, I originally believed that the phrase "aseptically disinfecting" as used in the patents precluded the use of oxonia as the sterilant, because the specification stated that the "aseptic filler must . . . use an FDA (Food and Drug Administration) approved sterilant" ('013 patent, col. 1, l. 48-50; '188 patent, col. 1, l. 46-48) and it was undisputed that "hydrogen peroxide was the only FDA approved sterilant at the time of filing". Steuben's PTAB Response, [427-14], p. 41.

However, I no longer hold that view. While patent claims must be given "the meaning that the term would have to a person of ordinary skill in the art in question ["POSITA"] at the time of the invention, i.e., as of the effective filing date of the patent application", Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005), proper construction "must begin and remain centered on the claim language itself". Source Vagabond Systems Ltd. v. Hydrapak, Inc., 753 F.3d 1291, 1299 (Fed. Cir. 2014); Fisher-Price, 2015 WL 2401887, *1. Claim 40 of the '188 patent states that "the step of aseptically disinfecting . . . includes a measuring device . . . wherein the sterilant is peroxyacetic acid and hydrogen peroxide". [426-3], CM/ECF p. 30, col.

6, l. 23-26. Neither a POSITA nor this court may "revise or ignore the explicit language" of that claim. Phillips, 415 F.3d at 1327; Duraflame, Inc. v. Hearthmark, LLC, 2013 WL 594241, *9 (N.D. Cal. 2013) ("a self-defining phrase [is] in no need of construction").

In arguing for a construction of "aseptically disinfecting" which would preclude the use of oxonia as the sterilant, some defendants point to the specification's use of the phrase "the present invention". However, while "a patentee's consistent reference to a certain limitation or a preferred embodiment as 'this invention' or the 'present invention' can serve to limit the scope of the entire invention . . . . use of the phrase 'present invention' or 'this invention' is not always so limiting, such as where the references to a certain limitation as being the 'invention' are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent." Absolute Software, Inc. v. Stealth Signal, Inc., 659 F.3d 1121, 1136 (Fed. Cir. 2011).

While these defendants also refer to certain statements made by Steuben in the prosecution history, I do not find those statements to be controlling: "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes". Phillips, 415 F.3d at 1317.

Defendants acknowledge that "aseptically disinfecting . . . has to be construed consistently across the patents because they're related". April 10, 2018 proceeding [500], pp. 16-17.[3] Therefore, since the phrase "aseptically disinfecting" as used in the '188 patent expressly

[3] *See also* Abtox, Inc. v. Exitron Corp., 131 F.3d 1009, 1010 (Fed. Cir. 1997) ("it would be improper to construe this term differently in one patent than another, given their common ancestry"); NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1293 (Fed. Cir. 2005) ("[b]ecause NTP's patents all derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents").

lists peroxyacetic acid and hydrogen peroxide (a/k/a oxonia) as the sterilant, I may not construe that same phrase elsewhere (in the '013 or other related patents) in a manner which would necessarily preclude its use.

Nevertheless, since "claims must be construed so as to be consistent with the specification, of which they are a part" (Phillips, 415 F.3d at 1316), I must still attempt to reconcile the specification's statement that the "aseptic filler must . . . use an FDA (Food and Drug Administration) approved sterilant" ('013 patent, col. 1, l. 48-50; '188 patent, col. 1, l. 46-48) with the fact that oxonia was concededly *not* an FDA approved sterilant as of the February 2, 1999 filing date. Steuben argues that "the cited statement ["FDA approved sterilant"] in the Background of the Invention section is just that - part of a general statement describing the field of the invention, state of the art, and problems to be solved, which include gaining FDA acceptance of an aseptic bottling system. This statement is . . . context for the description of Steuben's invention provided thereafter . . . . This description of the invention includes the use of oxonia in a system that 'will meet' the FDA's regulations governing aseptic packaging". Steuben's Memorandum of Law [492], p. 3.

Steuben suggests "that use of an 'approvable' sterilant . . . is usable in practicing Steuben's invention that 'will meet' the FDA regulatory requirements . . . . This inference is the more reasonable inference to draw where the patent expressly included the use of oxonia, which had not yet been used as a package sterilant in a system accepted by the FDA for commercial use." Steuben's Responses [492-1], p. 13. Although I previously criticized Steuben's attempt to substitute the word "approvable" for "approved" (Rule 56(f)(3) Notice [486], p. 2, n. 2), I now believe that Steuben is correct, since there is no other way to reconcile the requirement for an

FDA "approved" sterilant in the Background of the Invention with the fact that oxonia was not FDA approved as of the February 2, 1999 filing date.

However, "approvable" must mean approvable (even if not yet actually approved) by the FDA as of the effective filing date, rather than at a later date. "A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion", Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353 (Fed. Cir. 2010), and patent protection is limited "to those who actually perform the difficult work of 'invention' - that is, conceive of the complete and final invention with all its claimed limitations", thereby precluding "attempts to preempt the future before it has arrived". Id. Accordingly, the inventor must be "in full possession of the claimed subject matter on the application filing date". TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111, 1118 (Fed. Cir. 2001).

To summarize, I construe the phrase "aseptically disinfecting" to mean the use of a sterilant capable of being approved by the FDA, as of the effective patent filing date, to satisfy the "FDA level of aseptic" defined by the Federal Circuit in Nestle USA, Inc. v. Steuben Foods, Inc., 686 Fed. App'x 917, 918-19 (Fed. Cir. 2017).

B. Can the Patents Validly be Applied to Cover the Use of Oxonia?

35 U.S.C. §112(a) requires the patent specification to "contain a written description of the invention, *and* of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same" (emphasis added). These are "two separate . . . requirements",

(Ariad Pharmaceuticals, 598 F.3d at 1344), and Nestle's Final Invalidity Contentions assert that the '188 patent fails to satisfy both. 13-cv-892, [249-3], pp. 92-93.

My focus at this time is with §112's "written description" requirement, rather than its enablement requirement. *See* University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 921 (Fed. Cir. 2004) ("an invention may be enabled even though it has not been described"); Ariad Pharmaceuticals, 598 F.3d at 1352 ("although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described").

Because "claims that have not been invented . . . cannot be described" (Blue Calypso, LLC v. Groupon, Inc., 815 F.3d 1331, 1344 (Fed. Cir. 2016); Ariad Pharmaceuticals, 598 F.3d at 1353), determination of compliance with the written description requirement necessarily entails "the fundamental issue [of] whether [the inventor] actually invented the subject matter it claimed". University of Rochester, 358 F.3d at 930, n. 10. "The word 'invention' must refer to a concept that is complete, rather than merely one that is substantially complete." Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 66 (1998). It "requires conception and reduction to practice". Solvay, S.A. v. Honeywell International, Inc., 742 F.3d 998, 1000 (Fed. Cir. 2014).

While Steuben argues that conception and reduction to practice are relevant only to disputes over priority of invention (April 10, 2018 proceeding [500], pp. 8-9), I disagree. "If it is correct to read §112, first paragraph, as containing a requirement to provide a separate written description of the invention, as we hold here, Ariad provides no principled basis for restricting

that requirement to establishing priority . . . . Congress has not so limited the statute, and neither will we." Ariad Pharmaceuticals, 598 F.3d at 1349.

"The question of conception is properly directed to whether there was formation in the mind of the *inventor* of a definite and permanent idea of the complete and operative invention and whether every limitation of the count was known to the *inventor* at the time of the alleged conception." Bosies v. Benedict, 27 F.3d 539, 543 (Fed. Cir. 1994) (emphasis in original). "[S]imply because a person of skill in the art would understand things after reading the patent specification, does not establish that those same things were known to the applicant who wrote it." 2 Moy's Walker on Patents, §7:34 (4th ed.).

Therefore, the court must "look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea". Burroughs Wellcome Co. v. Barr Laboratories, Inc., 40 F.3d 1223, 1232 (Fed. Cir. 1994). The inventor's "actual possession or reduction to practice [of the invention] outside of the specification is not enough. Rather . . . it is the specification itself that must demonstrate possession". Ariad Pharmaceuticals, 598 F.3d at 1352.

Steuben contends that the use of oxonia to obtain FDA approval is an "aspect of [Taggart's] invention" (Markman hearing [485], p. 29). Although "Taggart didn't invent oxonia", he "said I can use that one too". Id. He expressly listed the use of oxonia for the sterilant as a limitation in claim 40 of the '188 patent ([426-3], CM/ECF p. 30, col. 6, l. 23-26), and "every limitation is material. Each element contained in a patent claim is deemed material to defining the scope of the patented invention". DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1016-17 (Fed. Cir. 2006).

Therefore, for purposes of determining inventorship, the critical question is whether (as of the February 2, 1999 filing date) Taggart had "a definite and permanent idea of the complete and operative" use of oxonia as the sterilant. Bosies, 27 F.3d at 543. While Steuben suggests that "in some cases you cannot rely on inventor . . . deposition testimony to invalidate a claim" (April 10, 2018 proceeding [500], p. 39), in this case I fail to see how Taggart's testimony (discussed at pp. 3-5 of my Second Rule 56(f)(3) Notice [497]) could lead to any other conclusion.

At the Markman hearing, Steuben argued that "those skilled in the art in 1999 well knew that oxonia could be used as a sterilant, that it was coming . . . . [Taggart] knew it was coming, and he described it in his patent . . . . he recognized it was coming, he claimed it." [485], pp. 29, 34, 88. However, in determining inventorship, there is a critical difference between what "is coming" and what has arrived. That distinction was noted in Medtronic Navigation, Inc. v. BrainLab Medizinische Computersysteme GmbH, 222 Fed. App'x 952 (Fed. Cir. 2007), involving the question of whether an inventor could claim to have invented an "optical tracking system" which he mentioned in his specification. Giving considerable weight to the inventor's testimony, the court concluded that he could not:

> "[I]t is true that the minimal one sentence reference to an optical tracking system is a mention of an optical tracking system. However, the remainder of the specification describes acoustic systems. There is no enabling description of how to make and use an optical tracking system . . . . Moreover, the inventor himself stated . . . that 'we weren't aware of any commercial optical tracking system that was available' and 'it seemed at the time that this would be an obvious development, that it would be coming in time. It was just that *at this time that we were writing this, that such a system wasn't available to us*' Thus, rather than being a disclosure of an optical system sufficient to support . . . a claim as including an optical system, it was merely an attempt to preempt the future before it has arrived." Id. at 956-57 (emphasis in original).

Just as in Medtronic, although he mentioned oxonia as a possible strerilant in the patent specification, Taggart provided no details which would indicate that he had "a definite and permanent idea of [its] complete and operative" use. In order to "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed", the specification must "sufficiently disclos[e] . . . the technologic knowledge upon which the patent is based". Ariad Pharmaceuticals, 598 F.3d at 1351, 1355. "[T]he level of detail required . . . varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." Id. at 1351.

Taggart provided no "technologic knowledge" as to the use of oxonia, because he had none to provide. While acknowledging that "much more testing . . . would be required" for an unapproved sterilant such as oxonia ([427-11], p. 198) and stating that "if some testing was done and the right data was presented to the FDA, they might approve it" (id., p. 227), he conducted no such testing. Therefore, like the inventor in Medtronic, Taggart's alleged belief that that FDA approval "was coming" ([485], pp. 34, 88) was nothing more than "an attempt to preempt the future before it has arrived". Medtronic, 222 Fed. App'x. at 957, Ariad Pharmaceuticals, 598 F.3d at 1353. *See also* Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336, 1350 (Fed. Cir. 2013) ("the written description requirement prohibits a patentee from leaving it to the industry to complete an unfinished invention").

C. The Next Steps

While the parties and I had initially contemplated that validity-related discovery and dispositive motions would follow the completion of claim construction, L. Pat. R. 1.3 authorizes the court, *sua sponte*, to modify the deadlines established under the Rules "based upon

the circumstances of any particular case". "The Court may sua sponte . . . modify the obligations and deadlines of the [local patent rules] based on the circumstances of any particular case when it will advance the just, speedy, and inexpensive determination of the action." Thorne Research, Inc. v. Atlantic Pro-Nutrients, Inc., 2016 WL 5374121, *1 (D. Utah 2016).

Resolution of the question of whether the patents validly apply to the use of oxonia appears to be case-dispositive for those defendants who use that sterilant. *See* March 23, 2018 proceeding [496], pp. 32-33. Therefore, I see no reason why that question should not be addressed now. "[D]istrict courts are widely acknowledged to possess the power to enter summary judgments *sua sponte,* so long as the losing party was on notice that [it] had to come forward with all of [its] evidence." Celotex Corp. v. Catrett, 477 U.S. 317, 326 (1986); Fed. R. Civ. P. 56(f)(3).

"Although section 282 of the Patent Act places the burden of proof on the party seeking to invalidate a patent, it does not foreclose the possibility of that party demonstrating that the patent in suit proves its own invalidity." University of Rochester, 358 F.3d at 930. "After all, it is in the patent specification where the written description requirement must be met." Id. at 927. Therefore, summary judgment may be appropriate where "no reasonable juror could find that [the] disclosure was sufficiently detailed to enable one of skill in the art to recognize that the [inventor] invented what is claimed". Id.

While "invalidity for lack of written description is a question of fact, expert testimony is not always required to prove invalidity. In some cases, the patent itself may evidence invalidity." Lucent Technologies, Inc. v. Gateway, Inc., 2007 WL 1449804, *2 (S.D. Cal. 2007). With regard to claim 40 of the '188 patent, this appears to be such a case.

A further conference will be held on April 30, 2018 at 2:00 p.m. to discuss a schedule for consideration of this issue, and for simultaneously proceeding with the remaining construction of those claim terms which are of importance those parties who do not use oxonia as the sterilant.

Dated: April 20, 2018

JEREMIAH J. MCCARTHY
United States Magistrate Judge